

## **REMARKS**

### ***I. The Objections Under Section 112***

In the Office Action, the Examiner made two rejections of Claim 9 under Section 112: failure to comply with the written description requirement and indefiniteness. Both rejections arose from Applicant's amending the application to read "normally wet or moist"

With this Amendment, the Applicant has amended Claim 9 to overcome these objections. Applicant amended Claim 9 to reflect the description in the specification, stating that the uses include applications on mucosal tissue that is wet or moist.

Additionally, Applicant's amendment clarifies the claim. The language "including wet or moist mucosal tissue" recites that the Applicant's invention is designed to be used in a moist environment some, but not all, of the time.

For the reasons set forth above, the Applicant submits that the claim, as amended, overcomes the Examiner's rejections based on Section 112.

### ***II. Substantive Rejections***

In this Official Action the Examiner rejected Claim 9 under Section 103 over Alwattari. Applicant concedes that Alwattari et. al. U.S. Patent No. 5,874,072 and Rechelbacher et. al. U.S. Patent No. 5,849,280 call for a member of a class of natural film forming polymers that includes both hydroxyethylcellulose and hydroxypropyl cellulose. However, applicant believes that Examiner's rejection was inappropriate for two reasons. First, one of ordinary skill in the art would not look to Alwattari or Rechelbacher, which both relate to aesthetic, external cosmetic products, to achieve a film for normally wet or moist mucosal tissue. Second, while two

substances may be members of the same class, they are not uniformly substitutable and therefore the disclosures in Rechelbacher and Alwattari should not render the present invention obvious.

Applicant's amendments have clarified the distinction between the Applicant's invention and the prior art by reciting with particularity that the Applicant's method is for forming a film on mucosal tissue that is wet or moist. Mucosal tissues line wet or moist internal organs and body cavities, exclusively internal areas of the human anatomy. These amendments differentiate the Applicant's invention from the external uses of the compound on non-mucosal tissues disclosed by Alwattari and Rechelbacher from the present invention.

One of ordinary skill in the art would not look to the cosmetic products disclosed by Alwattari and Rechelbacher. Products used internally on wet or moist mucosal tissue, such as the present invention, are judged by a different set of criteria than products used for a cosmetic use and most work in an environment that is quite different than the normally dry environment in which externally-applied cosmetic products are used. For example, an internally applied medical product has heightened safety issues, when compared to externally applied cosmetics. Further, the FDA process for the approval of a medicinal or internal use product is much more stringent than the approval process for a cosmetic. Because of the differing considerations, the use of the class of polymers disclosed by Alwattari and Rechelbacher would not be obvious to use in the wet or moist, internal mucosal environment of the Applicant's invention.

Additionally, it is very possible that a compound which is harmless when applied externally to the skin is not usable inside the body. The internal use of Applicant's invention on wet or moist mucosal tissues makes the use of hydroxyethylcellulose disclosed by Applicant different than the use disclosed in the prior art of Alwattari and Rechelbacher.

Members of the class of film forming polymers disclosed in Alwattari and Rechelbacher are not always equivalent and therefore not substitutable in all applications. Alwattari discloses natural polymers “from the group consisting of cellulose derivatives, algin, starch and its derivatives, guar and its derivatives, shellac polymers and mixtures thereof.” (Column 3, Lines 58-60), an extremely large class of materials. Members of this class are not uniformly substitutable. Examples of difficulty in substitution include the disclosure in Pomerantz (column 2, lines 27-30, stating hydroxyethylcellulose is not a substitute for hydroxypropyl cellulose) previously cited by Applicant. As such, the disclosure of a large class of compounds would not make it obvious to employ the Applicant’s compound in very different environment.

### ***III. Conclusion***

For the foregoing reasons, the Applicant submits that his claim, as amended, patentably distinguishes the Applicant’s invention from the art of record. Re-examination and re-consideration, culminating in the allowance of all the claim, is respectfully requested.

It is respectfully requested that the Examiner so find and issue a Notice of Allowance in due course.

### ***IV. Request for Appropriate Extension of Time***

If necessary, Applicant requests that this Response be considered a request for an extension of time for a time appropriate for the response to be timely filed. Applicant requests

that any required fees needed beyond those submitted with this Response be charged to the account of E. Victor Indiano, Deposit Account Number 50-1590.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "E. Victor Indiano", is written over a horizontal line.

E. Victor Indiano, #30,143